Non-Technical Abstract

In this study, approximately 27 patients will be treated with an investigational vaccine for breast cancer called Synchrovax BPL Vaccine to find out if it is safe and what side effects occur when the vaccine is injected into a lymph gland in the groin using a needle and a small pump. The Synchrovax BPL Vaccine is made from DNA, a natural substance from which the genes in all of our cells are made. The vaccine DNA includes the body's genetic blueprint for NY-ESO-1, a substance present on a lot of breast cancer cells, which can be recognized by the immune system. It is hoped that administration of this DNA vaccine will cause shrinkage of breast cancer tumors or delay the growth of breast cancer by boosting immunity to NY-ESO-1 on breast carcinoma cells.

In this trial, patients' blood cells will be tested for the expression of HLA-A2 blood type, which must be positive for patients to be eligible for this study. A preserved piece of patients' tumors will be tested for the presence of NY-ESO-1, the substance being vaccinated against. The patients' tumor will also be tested for the presence of ß-2 microglobulin, a protein that is involved in the activation of the immune system. The presence of NY-ESO-1 and ß-2 microglobulin on the tumor is required for entry to this trial. Patients will undergo a series of tests including CT scans to determine the size and extent of their tumor. To be eligible for this trial, patients must also have adequate function of the major organs and not have any serious viral infections.

Eligible patients will have an ultrasound test, which consists of painlessly bouncing sound waves off the body to locate a lymph gland the size of a dime in the groin. The lymph gland will then be punctured with a needle into which a thin plastic tube or catheter will be placed, and the needle removed. The plastic catheter will then be taped to the skin, and a small pump the size of a deck of cards will be used to pump the DNA vaccine continuously into the lymph gland for 96 hours. The correct position of the tip will be checked by another ultrasound at the end of the fourth day of each cycle of treatment. The initial eighteen patients on this trial will receive increasing doses of the DNA vaccine in groups of six patients at each dose. A final group of nine patients will receive the maximum or optimal dose of the DNA vaccine. All patients within a group will receive the same dose throughout all of their infusion cycles.

After the four-day or 96 hour period of injection of the DNA vaccine, there will be a nine-day rest period for a total of two weeks in a treatment cycle. The treatment cycle will be repeated four times for a total of eight weeks. Follow-up visits to the physician will be required after eight weeks from starting treatment. The total time of the study is at least eight weeks.

Blood samples (one tablespoon each) to measure important organ functions will be taken every other week beginning on the first day of treatment. Special blood tests (two tablespoons each) to measure the level of function of the immune system will be performed before treatment begins, just after the second treatment cycle, and just after the fourth treatment cycle. After eight weeks of treatment, patients will have repeated measurements and/or scans to measure their tumors. If there is evidence that the tumor has stayed the same or shrunk in response to the therapy, a repeated cycle of treatment with the DNA vaccine may be given.

No life threatening side effects or deaths were seen with previous tests or vaccines injected into the lymph nodes in patients with metastatic melanoma. The side effects related to injection of other DNA vaccines under the skin and in the veins included headache, fevers, weakness, joint pains and a rash that resolved without therapy. It is possible that the DNA vaccine will cause a condition called autoimmunity. Swelling of the joint with inflammation, pain, rashes and abnormalities of kidney and liver function might occur.

It is possible that there might be damage to the lymph gland that is injected. The lymph glands might become swollen or tender, or bleeding may occur. This has shown to be temporary, with the lymph glands returning to normal after the injections. The plastic catheter will be inserted in a sterile manner into the lymph gland, but infection at the injection site might occur.